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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,109	08/26/2003	Pramod B. Mahajan	1264C	9055

27310 7590 11/01/2006

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EXAMINER

BAGGOT, BRENDAN O

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/650,109	Applicant(s) MAHAJAN, PRAMOD B.	
	Examiner Brendan O. Baggot	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/26/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction / Election

1. The Office acknowledges the receipt of Applicant's Application filed 8/26/03.

Claims 1-18 are pending and examined in the instant application.

Sequence Listing

2. Applicant's computer readable format sequence listing has been entered.

Specification

3. Applicant's is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate. Applicant should note that parent application 09/835,654 has matured into a U.S. patent (U.S. Patent No. 6,646,182).

Claim Objections

4. Claims 1, 11 are objected to because of the following informalities: The Claims recite abbreviations, e.g., "%," which should be spelled out as "percent." Appropriate correction is required.

Claim Rejections - 35 U.S.C. §112, first paragraph, enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 and the protein encoded thereby, SEQ ID NO: 2, does not reasonably provide enablement for Mre11 transgenic plants expressing SEQ ID NO: 1, monocots or dicots expressing Mre11, or any plants or seeds with a Mre11 phenotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The *Wands* court set forth the enablement balancing test:

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the 'claims.'"

M.P.E.P. § 2164.01(a)

The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 19 24 (CCPA 1970).

Applicants claim are broadly drawn to transforming plants with any sequence having as little as 80% sequence identity to SEQ ID NO: 1 having non-exemplified and unspecified activity, any plant transformed therewith, and any seeds comprising the

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nucleotide of SEQ ID NO: 1.

Applicants teach SEQ ID NO: 1 and SEQ ID NO: 2. (See the sequence listing).

Applicants do not teach transforming plants with any sequence having as little as 80-90% sequence identity to SEQ ID NO: 1 as based on the entire coding regions of SEQ ID NO: 2 over unspecified portions and having non-exemplified and unspecified activity.

The Nature of the Invention

The claims are drawn to methods and compositions relating to transgenic plants. The invention is in a class of inventions which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The Breadth Of The Claims

The claims are broadly drawn to and encompass transforming plants with any sequence having as little as 80% sequence identity to SEQ ID NO: 1 over unspecified portions and having exemplified and non-exemplified activity. The broad language expressly includes sequences with less than 100% sequence identity to SEQ ID NO: 1 from any species with any sequence having any function, including sequences encoding proteins with no Mre11 or exonuclease activity. The claims are also drawn to transgenic plants with SEQ ID NO: 1.

Quantity Of Experimentation

The quantity of experimentation in this area is large since Applicant would have to identify homologs, clone the homologs, do enzyme assays to confirm the enzymes have activity, select the homologs with high activity, transform a sufficient number of plants to offset position effects, select out the high copy number transformants, and screen the transformants for high expressing lines. This effort is an inventive, unpredictable and difficult undertaking in itself. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The Unpredictability of the Art and the State of the Prior Art

There is abundant prior art to suggest that identifying proteins via percent identity alone is difficult, unpredictable and unsuccessful.

It is well established that sequence similarity is not sufficient to determine functionality of a coding sequence. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar function's" (the last sentence of the first paragraph of page 2484). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph).

Additionally, Bundock, et al., (2002) The Plant Cell, Vol. 14, 2451-2462) teaches

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that Mre11 transgenic plants were dwarf, sterile, and showed numerous developmental defects. (page 2457, right column).

Working Examples

The specification has no working examples of sequences which are 80% identical to SEQ ID NO: 1, no working examples of any protein with demonstrated exonuclease activity, and no working examples of viable, reproducible transgenic plants or seeds therefrom with demonstrated Mre11 activity or any viable phenotype. That no transgenic plant data is presented, when taken with the teachings of Bundock, supports an inference that Applicant's plants were nonviable.

Guidance in the Specification

The specification, while suggesting the use of the SEQ ID NO: 1, did not provide significant guidance on how to overcome art recognized problems in identifying homologs based on sequence identity alone, and as discussed above, how to prevent sterility and non-viable phenotypes seed in Mre11 transgenic plants. (Bundock @ 2457).

Level of Skill in the Art

The level of skill in the art is deemed to be high.

In the instant case, along with the absence of working examples, the relatively small amount of guidance in the specification, the unpredictability in the art and the

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large amount of experimentation that would be necessary to achieve function balanced only against the high skill level in the art, it is concluded that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Without sufficient guidance, determination of exonuclease sequences having the desired biological characteristics and without guidance on how to overcome the sterility and harsh phenotypes seen in Mre11 transgenic plants, it is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. *See In re Wands* 858 F.2d 731, 8 USPQ2d 1400 Fed. Cir, 1988)

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art, balanced only against the high level of skill in the art as discussed above, undue trial and error experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 112, 1st, paragraph, written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claims are broadly drawn to transforming plants with any sequence having as little as 80% sequence identity to SEQ ID NO: 1 over unspecified portions of SEQ ID NO: 1 and having non-exemplified and unspecified activity.

Applicants prophetically describe transforming corn with a single nucleotide sequence, SEQ ID NO: 1, (See Specification, example 8, A., page 73) via gun transformation and via *Agrobacterium* mediated transformation (See Specification, example 8, B., page 74) in some events.

Applicants do not describe transforming any plant with any gene, with any sequence having as little as 80%-90% sequence identity over unspecified portions to SEQ ID NO: 1, or having non-exemplified or unspecified activity. Applicants do not describe a plant transformed with SEQ ID NO: 1 with any viable, reproducible phenotype nor a direct assay of the enzyme encoded by SEQ ID NO: 1 with demonstrated activity. Accordingly, the specification fails to provide an adequate written description to support the genus of Mre11 encompassed by the percent identity language as set forth in the claims.

The Federal Circuit has clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the

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absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. *See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at

1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of

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sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See The Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 11-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu, (2004/0034888, Published 19 February 2004, SEQ ID NO: 31304 which is a continuation of application US-09/304517, filed 6 May 1999). Liu teaches a 332 base pair EST fragment from corn having 91.1% sequence identity to SEQ ID NO: 2, recombinant cassettes (paragraph 8), nonhuman monocot or dicot host cells (paragraph 67), transgenic plants (paragraph 21), soy, cotton, rice, canola, (paragraph 21), and transgenic seed (claim 3) . Thus, the reference teaches all the limitations of the Claimed

invention.

8. The following is a statement of reasons for the indication of allowable subject matter: SEQ ID NO: 1 is deemed free of the prior art in light of the failure of the prior art to teach or reasonably suggest an isolated polynucleotide comprising SEQ ID NO: 1. For SEQ ID NO: 1, the closest prior art identified through sequence searches was Levin, et al., (GenEMBL Database from US-09/480921B, filed 11 January 2000, U.S. Pat. No. 6387637), SEQ ID NO: 7 from *Arabidopsis* with ~~27.2~~27.2% sequence identity to SEQ ID NO: 1. (result No. 12). While Levin teaches a sequence with 27.2% homology, Levin does not teach an enzymatic function.

9. No Claim is allowed.

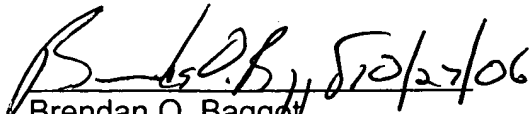
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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